



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 28, 2020

Jean Claude Marcelin
Senior Regulatory Affairs Manager
PDI, Inc.
400 Chestnut Ridge Road
Woodcliff Lake, NJ 07677

Subject: PRIA Label Amendment – Adding Efficacy Claims
Product Name: Project Flash Wipes
EPA Registration Number: 9480-16
Application Date: 01/28/2020
Decision Number: 564936

Dear Mr. Marcelin:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance Assurance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

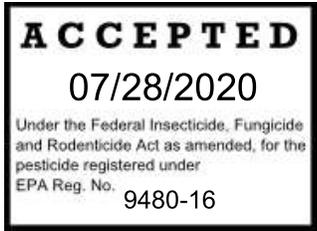
Sincerely,

A handwritten signature in black ink, appearing to read 'J. Varco', followed by a period.

Joseph Varco
Acting Product Manager, Team 33
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs

Enclosure

PROJECT FLASH WIPES



Alternate brand names:

Sani-HyPerCide [™] [®] GERMICIDAL DISPOSABLE WIPE
Sani-Cloth® HyPerCide [™] [®] GERMICIDAL DISPOSABLE WIPE
Sani-HP [™] [®] GERMICIDAL DISPOSABLE WIPE

Sani-HyPeroxide [™] [®] GERMICIDAL DISPOSABLE WIPE
Sani-Cloth® HyPeroxide [™] [®] GERMICIDAL DISPOSABLE WIPE
Sani-Cloth® HP [™] [®] GERMICIDAL DISPOSABLE WIPE

ACTIVE INGREDIENTS:

Hydrogen Peroxide.....	4.04%
<u>OTHER INGREDIENTS</u>	95.96%
TOTAL	100.00%

[Does not include the weight of the [cloth] [towelette] [or] [wipe]]

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See [back][outer] [carton] [side] [container[s]] [inside] [panel] for additional precautionary statements

[CONTAINS:] [or Net Contents] [and/or Net Wt.] _____ oz. (g) [or lbs. (kg)]
_____ [# OF CLOTHS] [Premoistened] [Wet] WIPES [SIZE of each cloth]

EPA Reg. No.: 9480-16
EPA Est. No.: 9480-NY-1
Or

EPA Est. No. A=9480-NY-1, B=72956-AR-1
Alpha character will precede batch code on product [OR Beginning of batch code indicates Est No.]

[Manufactured by [or for]]:
Professional Disposables International, Inc. (PDI)
400 Chestnut Ridge Road, Woodcliff Lake, NJ 07677 [USA]
[For information call:] [phone number to be inserted]
[Made in [USA] [of] [with] [domestic and [foreign] [imported] materials] [insert country]]

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[On any panel]

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using toilet.

FIRST AID:

If in eye[s]: Hold eye[s] open, rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or healthcare professional [or doctor] for treatment advice.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or healthcare professional [or doctor] for treatment advice.

Have the product container or label with you when contacting a poison control center or healthcare professional [or doctor] or going for treatment. For additional information or in case of emergency contact the Poison Control Center toll free at 1-800-222-1222.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. [See directions for use on container[s] inside.] [Consult [equipment] manufacturer's instructions prior to use.] [[For surfaces,] Test wipe on small inconspicuous area before use.]

[Use one of the following as applicable to type of container.]

[TO DISPENSE] [TOWELETTES] [or WIPES] [or TOWELS] [or CLOTHS]:

GENERIC:

Open lid. Pull out wipe. Close lid tightly.

CONTAINER or CANISTER

Remove lid [.] [and discard inner seal] [from] [container or canister]. Find center of roll, remove first wipe for use, twist corner of next wipe into a point and thread through the hole in the [container or canister] lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out at an angle. When not in use keep [center cap of] lid closed to prevent moisture loss.

BOX:

Open along perforations as indicated. Remove packets as needed.

PACKET or PACKAGE:

Tear open packet [or package]. Unfold wipe and use as directed.

[For use on small single packets only: [Not labeled for individual sale [or distribution] and/or [See dispenser [or container or box or case or outer packaging] for [additional or full label] information].

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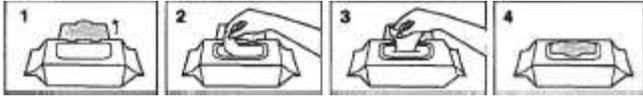
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[SOLO® PAK] [Portable Pack] [Soft Pack][Flow Pack][Eco-Pak]:

Open package lid. Completely remove inner seal. Pull out wipe [at an angle] [towards you through orifice or opening]. [(The next wipe pops up automatically.)] Snap lid closed after use to retain moisture.



KEEP SOLO® LID CLOSED WHEN NOT IN USE

SOLO® is a registered trademark of Nice-Pak Products, Inc.

REFILL [PACKET] [or PACKAGE] [or POUCH][or CANISTER][or BUCKET][or PAIL][or DISPENSER]:

This refill package is made for use only in a [product name] container [or canister or bucket or pail or dispenser]; do not use this product in a container [or canister or bucket or pail or dispenser] for another product. Do not use the refill wipes in a container [or canister] [or bucket] [or pail][or dispenser] that is cracked or broken. Discard the cracked or broken container [or canister] [or bucket] [or pail][or dispenser] in accordance with the container [or canister][or bucket][or pail][or dispenser] disposal instructions on the label.

[Option 1]

Remove [entire] lid from container [or canister or bucket or pail or dispenser]. Tear open refill packet [or package] [or pouch] at notch [or mark] [or arrow] and place [wipe] roll in empty container [or canister or bucket or pail or dispenser]. Follow information on container [or canister or bucket or pail or dispenser] to dispense wipes.

[Option 2]

Remove [entire] lid from container [or canister or bucket or pail or dispenser]. Tear open refill packet [or package] [or pouch] at notch [or mark] [or arrow]. Place [entire] refill packet [or package] [or pouch] of wipes in empty container [or canister or bucket or pail or dispenser]. Follow information on container [or canister or bucket or pail or dispenser] to dispense wipes.

CONTAINER [or CANISTER or BUCKET or PAIL or DISPENSER] [numbers optional]

1. Remove [the] lid [from] [the] [pail or bucket or container or canister or dispenser].
2. [Press] open [the] [dispenser at center of [the] lid].
3. Open [the] refill [packet] [package] [pouch] then place in [pail or bucket or container or canister or dispenser].
4. Locate [the] first wipe at [the] center of [the] roll.
5. Feed [the] first wipe through [the] dispensing orifice.
6. Reapply [the] lid [to] [the] [pail or bucket or container or canister or dispenser.]
7. Dispense [the] wipe.

FOR THE REFILL[S] [PACKET] [PACKAGE] [POUCH] [or CANISTER][or BUCKET][or PAIL][or DISPENSER]:

1. Remove [the] lid from [the] [pail or bucket or container or canister or dispenser.]
2. Remove [the] empty refill [packet] [package] [pouch] material from [the] [pail or bucket or container or canister or dispenser.]
3. [Press] open [the] dispenser at center of [the] lid.
4. Open [the] refill [packet] [package] [pouch] then place in [pail or bucket or container or canister or dispenser].
5. Locate [the] first wipe at [the] center of [the] roll.
6. Feed [the] first wipe through [the] dispensing orifice.
7. Reapply [the] lid [to] [the] [pail] [or bucket or container or canister or dispenser].
8. Dispense [the] wipe.

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DISINFECTING DIRECTIONS

TO DISINFECT [AND DEODORIZE] HARD, NONPOROUS SURFACES: If present, use a wipe to remove visible soil loads prior to disinfecting. Use [a] [clean] wipe to thoroughly wet surface. Allow surface to remain visibly wet for one (1) minute [OR for (60) seconds]. [Use [additional] [enough] wipe(s) [, if needed,] to ensure [continuous] one (1) minute [OR (60) seconds] visibly wet contact time.] [Repeated use of the product may be required to ensure that the surface remains visibly wet for one (1) minute [OR for (60) seconds].] Let air dry. A potable water rinse is required for food contact surfaces. [*When TB is included on the label, add the following:*] A precleaning step is required to kill *Mycobacterium bovis* BCG (TB). These directions also apply to *Mycobacterium bovis* BCG (TB) at 69.8°F (21°C). [*If label includes cleaning claims for grease, soap scum, grime, dirt, messes, soil, add the following as the first sentence:* A precleaning step is required for [grease], [soap scum], [grime], [dirt], [messes], [soil].]

CLEANING DIRECTIONS

[TO CLEAN: Wipe surface with a towelette until clean. Let air dry.] (*Cleaning directions must be used when cleaning claims are made on product label.*)

[ULTRASOUND TRANSDUCERS AND PROBES: For use on external surfaces of ultrasound transducers, scopes [and] [or] probes only prior to high-level disinfection [(HLD)].

To preclean prior to high-level disinfection [or HLD]: Preclean gel from external surface of ultrasound transducer, scope, [and] [or] probe[s] by using a clean washcloth or [germicidal] wipe. Then, follow instructions to disinfect.]

[The following instructions are to be included on production labels when claims against HIV, and/or HBV and/or HCV are listed; one, two or all three of the viruses may be included on claims and directions in production labels.]

†KILLS HIV-1 (AIDS VIRUS), HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS [AND PRECLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS [AND PROBE[S]] PREVIOUSLY SOILED WITH BLOOD/ BODILY FLUIDS at room temperature (68°-77°F) or (20°- 25°C) in healthcare or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or bodily fluids, and in which the surfaces/objects likely to be soiled with blood or bodily fluids can be associated with the potential for transmission of Human Immunodeficiency Virus Type 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV),and Hepatitis C Virus (HCV).

†SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) ON SURFACES/OBJECTS SOILED WITH BLOOD/ BODILY FLUIDS:

Personal protection: When handling HIV-1 (AIDS Virus), HBV or HCV infected blood or bodily fluids; wear disposable protective gloves, protective gowns, masks and eye coverings, per facility protocol.

Cleaning procedure: All blood and other bodily fluids must be thoroughly cleaned from surfaces and objects before disinfection by the [germicidal] wipe.

Disposal of infectious materials: Used wipe that may be contaminated with blood and other bodily fluids should be disposed of according to local regulation for infectious waste disposal.

Contact time: Use [germicidal] wipe to thoroughly wet surface. Allow surface to remain visibly wet for one (1) minute

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[OR for (60) seconds]. [Use [additional] [enough] wipe(s) [if needed,] to ensure [continuous] one (1) minute [or (60) seconds] visibly wet contact time.][Repeated use of the product may be required to ensure that the surface remains visibly wet for one (1) minute [for (60) seconds].] Let air dry.

[The following instructions are to be included on production labels when *C.difficile* spores claims are listed.]

Special Instructions for Cleaning Prior to Disinfection Against *Clostridium difficile* [spores].

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks and eye covering [per facility protocol].

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with a clean cloth, mop, and/or sponge saturated with the disinfectant with sporicidal activity product. Cleaning is to include [vigorous] wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Waste Disposal: Materials used in the cleaning process that may contain feces/waste are to be disposed of immediately in accordance with local regulations for disposal of infectious materials.

Contact time: Use [germicidal] wipe to thoroughly wet surface. Allow surface to remain visibly wet for five (5) minutes. [Use [additional] [enough] wipe(s) [if needed,] to ensure [continuous] five (5) minutes visibly wet contact time.] [Repeated use of the product may be required to ensure that the surface remains visibly wet for five (5) minutes.] Let air dry.

[The following instructions are to be included on production labels when claims against *C.auris* is listed.]

Special Instructions for cleaning prior to disinfection against *Candida auris*.

Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks, and eye coverings [per facility protocol].

Cleaning Procedure: Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with [product name] [this product]. Pre-cleaning is to include vigorous wiping and/or scrubbing and all visible soil is removed. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading the organism. Restrooms are to be cleaned last. Do not reuse soiled cloths.

Infectious Waste Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

Contact time: Use [germicidal] wipe to thoroughly wet surface. Allow surface to remain visibly wet for one (1) minute [OR (60) seconds]. [Use [additional] [enough] wipe(s) [if needed,] to ensure [continuous] one (1) minute [or (60) seconds] wet contact time.] [Repeated use of the product may be required to ensure that the surface remains wet for one (1) minute [OR (60) seconds].] Let air dry.

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[Terminal Sterilant Disclaimer per PR Notice 94-4]

[The following paragraph must be used if hospital and healthcare use sites are on the label.]

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean and decontaminate critical or semi-critical medical devices prior to sterilization or [high level disinfection] [or HLD].

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage or disposal. *[Statement not required for residential or household use products.]*

[Use storage and disposal Statement A if canister, bucket, pail or refill dispenser directions used. Use storage/disposal Statement B if Solo Pak, Portable Pack, Soft Pack, Flow Pack, Eco-Pak, Packet, Pouch, or [refill packet/package] directions used.]

[Statement A:]

Storage: Store this product in a cool, dry area, away from direct sunlight. When not in use, keep [center cap of] lid closed to prevent moisture loss.

Towelette Disposal: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.

Canister [or Container or Bucket or Pail or Dispenser] Disposal: Nonrefillable canister [or container or bucket or pail or dispenser]. Do not reuse or refill this canister [or container or bucket or pail or dispenser]. Offer for recycling. If recycling is not available, put in trash collection.

[If refillable dispenser is being used, substitute the following: Refill Package [or Canister or Container or Bucket or Pail or Dispenser] Disposal: Offer for recycling. If recycling is not available, discard in trash.]

[Statement B:]

Storage: Store this product in a cool, dry area, away from direct sunlight. **Towelette Disposal:** Do not reuse towelette. Dispose of used towelette in

trash. Do not flush in toilet. **Packet [or Package or Pouch or Container or Dispenser] Disposal:** Put empty Solo® Pak [or Portable Pack or Soft Pack or Flow Pack or Ecopak or [refill] packet or packaging or pouch] in trash collection.

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[Optional Use Sites]

Table 1: Hard, nonporous use sites/surfaces

[Areas of Use:] [Hospital and Healthcare Settings:] For use on hard, nonporous surfaces in [or on][:]			
[Optional Use Sites]			
Ambulances	Ambulatory Surgical Centers (ASC)	Anesthesia equipment surfaces	Ambulance equipment surfaces
Bed railings	Bladder scan	Blood glucose meters	Blood pressure cuffs
CAT Labs	CCU	Critical Care Units (CCU)	Central Supply
Cabinets	Cardiac gym equipment	Cardiac monitors	Carts
Clinics	Chairs	Counters	Dental Offices
Dental chairs	Dental unit instrument trays	Dental countertops	Defibrillators
Doctors' Offices	Dopplers	Donation Centers ([blood][plasma][semen][milk][apheresis])	Dialysis Clinics
E.R.	Emergency Rooms	Emergency Medical Settings	Emergency Vehicles
Endodontic equipment such as apex locators	Exam tables	Electronic thermometers	Eye Surgical Centers
Gurneys	Healthcare Settings	Health Care Facilities	Home Health Care
Hospitals	Hospices	Intensive Care Units (ICU)	Isolation Areas
Isolettes	IV poles	IV pumps	ICU
[Interior and exterior surfaces of] infant incubators	[Interior and exterior surfaces of] infant warmers	Laboratories	Laundry rooms
Long Term Care Centers	Laboratory equipment and surfaces	Loupes	Medical Intensive Care Units (MICU)
Newborn nursery	Nursing homes	Nursing rooms	Neonatal Intensive Care Units (NICU)
Operating Rooms (OR)	Oncology Facilities	Ophthalmic Offices	Orthopedics
Out-Patient Surgical Centers (OPSC)	Operatory light switches	Ophthalmoscopes	Otoscopes
Operating room tables and lights	Oxygen hoods	Patient lift equipment	Physical Therapy (PT) equipment surfaces
Patient Care Areas	Patient Rooms	Pediatrics	Pediatric Intensive Care Units (PICU)
Physical therapy	Physicians' offices	Pulse oximeter	Post-Operative Care Unit (PACU)
Radiology Unit	Radiology equipment	Respiratory therapy areas	Recovery Rooms
Rehabilitation center	Rest rooms	Skilled Nursing Facility	Surgery Intensive Care Unit (SICU)
Surgical Centers	Surgery areas	Slit lamps	Spine back boards
Stretchers	Stools	Tables	Telemetry equipment
Stethoscopes	Telephones	Toilet seats	Transport vehicles
Tympanic thermometers	Urgent Care Centers	Workstations on wheels (WOW)	X-Ray

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Hard, nonporous outside surfaces of: dialysis machines	Hard, nonporous outside surfaces of: anesthesia machines and respiratory therapy equipment	Hard, nonporous outside surfaces of: apheresis machines	Hard, nonporous outside surfaces of: diagnostic equipment
Hard, nonporous outside surfaces of: toilets	Hard, nonporous outside surfaces of: patient monitoring equipment	Hard, nonporous outside surfaces of: patient support and delivery equipment	Hard, nonporous outside surfaces of: pulp testers and motors
Hard, nonporous outside surfaces of: ultrasound monitors	Hard, nonporous outside surfaces of: ultrasound transducers and probes.		

Table 2: Surface Materials

Hard, Nonporous Surface Materials:		
ABS plastic	Aluminum	Brass
Copper	Corian ^{® 2}	Chrome
Formica ^{® 1}	Glass	Glazed ceramic
Laminate Surfaces	Linoleum	Polycarbonate
Polyester	PVC	Plexiglas ^{® 3}
Porcelain	Polybutylene Terephthalate (PBT)	Rubber
Stainless Steel	Treated Wood surfaces	Titanium
Vinyl	Zinc	

¹ Formica [®] is a [registered] trademark of The Diller Corporation

² Corian [®] is a [registered] trademark of E. I. du Pont de Nemours and Company

³ Plexiglas [®] is a [registered] trademark of Arkema, Inc.

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[Symbols including asterisks, bullets or footnotes and similar may be used to designate categories of organisms.]
 [ATCC numbers are not required to be listed on production label. Organisms may be listed in a table and in any order.]

Table 3 : List of Disinfection Organisms
Disinfection

Contact Time	Microorganism	Identification Number	Antibiotic Resistance demonstrated
1 Minute	Antibiotic Resistant Bacteria		
	Carbapenem Resistant - <i>Klebsiella pneumoniae</i>	[ATCC BAA-1705]	[(CRKP)]
	<i>Acinetobacter baumannii</i> – Multidrug Resistant (MDR)	[ATCC 19606]	[Effective against organism resistant to Gentamicin, Trimethoprim/Sulfa and Intermediate resistance to Cefepime, Ceftazidime, Ceftriaxone]
	Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA)	[ATCC 33592]	
	Vancomycin Resistant <i>Enterococcus faecalis</i> (VRE)	[ATCC 51575]	
	NDM-1- Positive <i>Enterobacter cloacae</i>	[CDC 1000654]	
	ESBL Positive <i>Escherichia coli</i>	[ATCC BAA-196]	
	Bacteria		
	<i>Salmonella enterica</i>	[ATCC 10708]	
	<i>Pseudomonas aeruginosa</i>	[ATCC 15442]	
	<i>Staphylococcus aureus</i>	[ATCC 6538]	
	Bloodborne Pathogens		
	*Hepatitis B virus (HBV) - Duck HBV†		
	*Hepatitis C virus (Human) (HCV) – Bovine Diarrhea Virus† [Strain NADL, American BioResearch Lab]		
	*HIV-1+ (AIDS virus) [Strain HTLV-III _B]		
	Non-Enveloped Viruses*		
	*Adenovirus type 5 [Strain Adenoid 75]	[ATCC VR-5]	
	*Rhinovirus type 1A [Strain 2060]	[ATCC VR-1559]	
	*Rotavirus [Strain WA]	[ATCC VR-2018]	
	* Norovirus (Feline Calicivirus) [Strain F-9]	[ATCC VR-782]	
	Enveloped Viruses*		
	*Herpes Simplex virus type 2 [Strain G]	[ATCC VR-734]	
	*Influenza A virus (H3N2) / Strain A/Hong Kong 8/68	[ATCC VR-544]	
	*Respiratory Syncytial virus (RSV), [Strain Long]	[ATCC VR-26]	

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	Pathogenic Fungi		
	<i>Candida albicans</i>	[ATCC 10231]	
	<i>Candida auris</i>	[AR-BANK #0381]	
	<i>Trichophyton interdigitale</i> [(Formerly known as) [(Tested as) <i>Trichophyton mentagrophytes</i>]]	[ATCC 9533]	
	Mycobacterium (TB) [Tuberculocidal]		
	<i>Mycobacterium bovis</i> BCG (Tuberculosis) (TB)		
5 min[utes]	C.difficile [Spores]		
	<i>Clostridium difficile</i> [spores]	[ATCC 43598]	

[Effective against all listed organisms in the presence of organic soil (5% blood serum)]
[Optional organism listings and claims:]

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[Note: The following Emerging Viral Pathogen claims will not appear on product labels]

Emerging Viral Pathogen Claims

This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large, Non-Enveloped Viruses
- Small, Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped virus	Adenovirus Type 5, Strain Adenoid 75 (ATCC VR-5)
Large, non-enveloped virus	Rhinovirus Type 1A, Strain 2060 (ATCC VR- 1559)
Small, non-enveloped virus	Rhinovirus Type 1A, Strain 2060 (ATCC VR- 1559) Feline Calicivirus, Strain F-9 (ATCC VR-782)

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, [nonporous surfaces]. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, nonporous surfaces]. Refer to the [CDC or OIE] website at [pathogen specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product Name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on [hard, nonporous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.

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Optional Claims and Descriptors [Note: Deodorizing directions must be used when deodorizing claims (claims involving odor control) are used]

Disinfecting Claims	
An effective method to deodorize and disinfect against odor-causing organisms on hard, nonporous surfaces [listed on this label]	An effective way to disinfect hard, nonporous [environmental] surfaces listed on this label.
An effective [Great][Appropriate][ideal][approach] [method] [process] [solution] [product][way] to [clean] [disinfect] [kill] [destroy] [against] [odor-causing] [bacteria] [germs] [norovirus] [viruses*] [cold & flu viruses*] [pathogens] [harmful] [fungus] [organisms][microorganisms] on hard, non-porous surfaces[fomite]	Antibacterial
[Antibacterial] [Antimicrobial] health club equipment wipe	Antimicrobial
Bacteria [and] [or virus*] [and] [or germ] fighting [formula]	Bactericidal
[Bactericidal], [Tuberculocidal], [Fungicidal], [and] [Virucidal*] [in] [1 [one] minute] [or 60 seconds]	[Bactericidal], [Tuberculocidal], [Fungicidal], [Virucidal*][and] [Disinfectant With Sporicidal Activity ^(A)] [(^A C. difficile [spores])]
Bathroom disinfectant	Broad Spectrum Disinfectant
Broad spectrum efficacy	Broad spectrum [microorganism coverage]
Can help reduce cross contamination on treated surfaces	[Convenient] [Portable] way to disinfect hard, nonporous surfaces
Demonstrates 99.9% reduction of [bacteria] [<i>insert bacteria</i>]	Deodorizes [,] [cleans,] and kills household germs* [<i>use at least two bacteria and two viruses from the organism list</i>]
Designed for killing [<i>Clostridium difficile</i>] [<i>or C. difficile</i>] [<i>or C.diff</i>] [spores] on hard, nonporous surfaces [in hospitals] [<i>or Insert area of use facility from pages 6 - 7</i>]	Demonstrates [99.9%] [log] reduction against [<i>Clostridium difficile</i>] [<i>or C. difficile</i>] [<i>or C.diff</i>] [spores] [in 5 [<i>or five</i>] minutes]
[Destroys] [Deactivates] [<i>Clostridium difficile</i> [spores]] [<i>or C.difficile</i> [spores]] [<i>or C.diff</i> [spores]] on hard, nonporous surfaces [in hospitals] [<i>or Insert area of use facility or from pages 6 - 7</i>]	Disinfects [grocery cart handles] [shopping cart handles] [grocery cart child seats] [shopping cart child seats]
Disinfect external hard, nonporous surfaces of ultrasound transducers and probes	[Disinfects] hard, nonporous surfaces
Disinfects precleaned hard, nonporous surfaces	Disinfects on the go
Disinfectant wipe	Disinfects [health club equipment] [treadmill handles] [elliptical handles] [exercise bike handles] [weight benches]
Disinfects [,] [cleans] [and deodorizes] hard, nonporous surface(s) [that people touch] [in] [just] [1 minute] [or 60 seconds]	Disinfectant With Sporicidal Activity ^(A) [(^A [<i>Clostridium difficile</i>] [or <i>C. difficile</i>] [spores])]
Effective against [<i>Clostridium difficile</i>] [<i>or C.difficile</i>] [<i>or C.diff</i>] [spores] [in 5 [<i>or five</i>] minutes]	Effective against bacteria and viruses* [<i>use at least two bacteria and two viruses from the organism list</i>]
Effective in the presence of 5% blood serum contamination	Effective against [:] [the following micro-organisms] [<i>list organisms</i>] on hard, nonporous surfaces

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Effective against a broad range of microorganisms	Everyday [disinfection] against [<i>list microorganism</i>]
[Five] [5] minute Disinfectant With Sporicidal Activity ^(A) [(^ [<i>Clostridium difficile</i>] [or <i>C.difficile</i>] [spores])]	Fungicidal
Germicidal* [Wipe] [<i>use at least two bacteria and two viruses from the organism list</i>]	Hard, nonporous surface disinfectant
[Helps] [kill(s)] odor-causing bacteria	Just [or simply] wipe exterior toilet surface [or bathroom] germs* away
[Kills] [Disinfects] Norovirus [<i>Feline Calicivirus</i>] in 1 [one] minute	Kills [<i>Clostridium difficile</i>] [or <i>C. difficile</i>] [or <i>C.diff</i>] [spores] [in 5 [or five] minutes]
[Kills][Effective against] [the following micro-organisms on hard, nonporous surfaces] [<i>list organisms</i>] [in][just] [one][1][minute][60 seconds]	Kills bacteria and viruses* [in the bathroom] [on the exterior toilet surfaces] [<i>use at least two bacteria and two viruses from the organism list.</i>]
Kills a wide range of pathogens	Kills bacteria in 1 minute
[Kills] [Effective against] 99.9% of [<i>Clostridium difficile</i>] [or <i>C. difficile</i>] [or <i>C.diff</i>] [spores] [in 5 [or five] minutes]	[Kills] [Effective against] MRSA [(Methicillin Resistant <i>Staphylococcus aureus</i>)] in 1 (one) minute
[Kills] [Effective against] CRKP [(Carbapenem Resistant <i>Klebsiella pneumoniae</i>)] in 1[or one] minute	[Kills] [Effective against] TB in [1] [one] minute
[Kills] [Effective against] the [spore form of] <i>Clostridium difficile</i> [or <i>C. difficile</i>]	[Kills] [Effective against] viruses* in [only] [1] [one] minute
Kills odor causing bacteria	Leaves [bathroom] [office] [and other sites listed on this label] disinfected [and smelling fresh]
[Kills][Effective against] [<i>Candida auris</i>] [or] <i>C. auris</i> in one [or 1] minute	[Kills][Effective against] <i>Candida auris</i>
Multi-purpose disinfectant	One [1] minute [or 60 seconds] [general] disinfectant[***] [***5 minutes for <i>C.difficile</i>]
One [1] minute [or 60 seconds] [kill] [contact] time reduces time to turnover room	One [1] minute [or 60 seconds] [contact time][***] [***5 minutes for <i>C.difficile</i>]
One [1] minute [or 60 seconds] [Bactericidal] [,] [Virucidal*] [,] [Fungicidal] [,] [and] [Tuberculocidal]	One [1] minute [or 60 seconds] [kill] [contact] time on [X] microorganisms
Overall 5 [OR five] minutes contact time	One-Step Disinfectant [<i>Grease and soap scum claims are not to be used on labeling with one-step disinfection claims. One step disinfectant claim should not be used for C.difficile.</i>]
One step[cleaner][disinfectant]**(**A precleaning step is required to kill <i>C.difficile</i> [spores] and <i>Mycobacterium bovis</i> (BCG))[(Tuberculosis)][(TB)]	Perfect for disinfecting [exterior toilet surfaces] [around the exterior toilet surface]

* [Product name] is virucidal against Adenovirus type 5, Hepatitis B virus (HBV), Hepatitis C virus (HCV), Herpes Simplex Virus type 2 (causative agent of genital herpes), HIV-1, Influenza A virus (H3N2)/Hong Kong strain (representative of the common flu virus), Respiratory Syncytial Virus [RSV], Rhinovirus type 1a, Rotavirus (Strain WA), and Norovirus (Feline calicivirus) in the presence of organic soil (5% blood serum).	
Surface disinfectant	Sani-HyPerCide ^(TM) [®] [Wipe] [Disinfectants]
Tuberculocidal	The 5-minute [germicidal+] [disinfectant wipe]
The 1-minute [germicidal+] [disinfectant wipe][^(f)][^(f) 5 minutes for <i>C.diff</i>]	Thick, heavy duty wipes are Bactericidal, Tuberculocidal and Virucidal* in 1 minute
[This product] reduces the spread of germs on most treated hard, nonporous surfaces	Thick, large wipe disinfects

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This product cleans, disinfects, and deodorizes hard, nonporous medical surfaces without any rinsing required[*].[*A thorough rinse with potable water is required for food contact surface.]	Tough on germs, [excellent] [or ideal] [or great] for everyday use
This product disinfects [and cleans major soils]	Tough on germs, easy on surfaces
Tough on germs, easy to use around patient[s] [areas]	[The] easy [and] [or convenient] way to disinfect
Use in places when you are concerned about bacteria [and] [or viruses*] [and] [or germs]	Use [or cleans] [and] [or disinfects] on hard, nonporous healthcare surfaces
Use where control of the hazards of cross contamination between treated surfaces is of prime importance	Use in public [or common places] where [bacteria [and] [or viruses*] [and] [or germs] may be of concern
[Use to] disinfect(s) hard, nonporous environmental surfaces listed on this label	Versatile disinfectant
[Wipes out] [Kills] viruses* and bacteria [including the flu virus* (*Influenza A/Hong Kong)]	[Wipes out] [Kills] [List organisms] in [just] [1 minute] [or 5 minutes]
[Wipes out] [Kills] [the] flu virus* (*Influenza A/Hong Kong)	Wipes are [Bactericidal], [Tuberculocidal,] [Fungicidal,] [Virucidal*] in 1 minute [or 60 seconds]
Virucidal*	

General Cleaning and Deodorizing Claims

Cleans with [minimal][virtually no] residue	Cleans [,] [Deodorizes,] and kills household germs* <i>[use at least two bacteria and two viruses from the organism list]</i>
Cleans [as it disinfects ^β] [and disinfects ^β] [^β When used according to disinfection directions]	Cleans [tough stains]
Cleans and disinfects without alcohol	Deodorize hard, nonporous surfaces [Use to]
Makes cleaning easier	Powers through tough messes
Removes [odors] [dirt]	[Use to] Deodorize hard, nonporous surfaces

Formula Related Claims

A hydrogen peroxide solution impregnated in a wiping cloth	Are pre-measured to [have][contains][deliver] the recommended amount of germicidal solution, wipe after wipe
Bleach-free [formula] <i>[this is included as useful info for users needing a bleach-free product]</i>	Compatible [for use on hard, nonporous surfaces commonly found in healthcare settings [listed on this label]]
Contains no VOC-emitting ingredients	Compatible [with equipment surfaces]

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Compatible with commonly used materials [in healthcare settings]	Compatibility tested
Does not contain bleach [<i>this is included as useful info for users needing a bleach-free product</i>]	Non-Bleach [<i>this is included as useful info for users needing a bleach-free product</i>]
Non-corrosive	No diluting or mixing required
Non-Bleach Sporocidal [^] ([^] [<i>Clostridium difficile</i>] or [<i>C. difficile</i> spores) [hospital] [disinfectant] [<i>this is included as useful info for users needing a bleach-free product</i>]	Proprietary Formulation [product]
Ready to Use [disinfectant] [wipe]	

Formula Related Claims	
Does not leave [visible] [residue][haze]	Dual action
Hydrogen peroxide [disinfectant with sporicidal activity] [formulation] [wipe] [RTU][formula]	Leaves virtually no [visible] [residue][haze]
Low streak formula	[Low] [minimal] residue [formula]
No mixing, measuring, [or rinsing] required	Prevents [mixing][measuring][dilution] errors
[Product name] [is] a Hydrogen peroxide pre-saturated wipe	[Product name] is pre-measured to have [OR contain] [OR deliver] the recommended amount of germicidal [OR bactericidal][OR virucidal*][OR fungicidal] [OR Tuberculocidal][disinfectant with sporicidal activity] [solution][formula] wipe after wipe
Requires no mixing or measuring and are ready-to-use	Ready to Use [disinfectant] [wipe]
Shelf-Stable formula	Unique Formula
Will not corrode surfaces	With a bleach-free formula [<i>this is included as useful info for users needing a bleach-free product</i>]

Packaging Related Claims	
[Convenient and] easy to use	Contains [number] canisters [plus] [and] [number] [refills]
Convenient [Size]	Close lid [after use][when not in use]
Designed for [EVS][ES][Environmental Services][housekeeping][services] [extra-large wipe in bucket and refill]	Designed for easy dispensing [and][or] [ease of use]
Dispenses [or Comes out] one wipe at a time	Dispenses one wipe at a time
Dispensing is effortless[!]	Easy [and] [or Better] [Dispensing] Lid [or Closure] [or Cap]
Easy to carry	Easy [to use] [to refill]
[Easy] [Convenient] [Portable] way to disinfect hard, nonporous surfaces	Easy [and convenient] way to [touch-up] [bathroom] [office] [and other sites listed on this label] everyday

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Easy to Open [or Thread]	Easy to pull wipes
[Easy] pop-up tub	Easy start lid [package]
Easy to [store] [and] [or stack]	Easier Than Ever to Use [or Pull] [Wipes] [Out] [!]
Easy to use design	Easy [to use] dispenser
Easy to Use Lid	Easy [to Use] Dispensing] [or Dispenser[!]]
Easy [and] [or Simple] [or Better] Dispensing[!]	Effortless dispensing[!]
Easy to use [package] [canister] [container] keeps [your] wipes moist	[Economical] Refill[s] [one] [1] [two] [2] [three] [3] [four] [4] [various numbers] -pack
[Economical] Refills [now] available	Includes_ count refill [pack] [contains] _ wipes
Moisture-lock lid	Multiple sizes available to meet disinfecting needs
Multi-pack	[Multi [-refill] pack]
No canister needed	Next wipe pops up automatically [every time] [!]
No threading [required]	One [wipe] at a time dispensing
[Please] keep lid closed	[Package] [<i>insert type of package</i>] made from [x%] recycled materials
Pop-up [dispensing] [top]	Recyclable [package]
[Refill] package contains [<i>various numbers</i>] [refill(s)]	Refill [size] [pack] [value pack]
Twin pack	Trial [pack]
X% reduction in packaging [material]	X% [more] [wipes] [free] [vs. Z count] [canisters] [packs]

<i>Towelettes Related Claims</i>	
[Absorbent] wipe	[Cloth-like texture][Textured] [strong] [for] [with] [cleaning] [and][or] [disinfecting] power
Durable, low-lint designed for sensitive equipment surfaces	Embossed wipe is low linting [for sensitive equipment surfaces]
[Extra] large [disinfecting] [Y" x Z" compared to our A" x B" size] wipe[s]	[Heavy] cloth-like towel
Larger wipe covers [more surface area] larger area [with less effort][!]	Larger, thicker wipe [with embossed design] (<i>may be used for 6 months on marketed label</i>)
Large[r] [wipe][s]	Low linting [Low tearing]
No [pinched fingers] [rips] [tears]	New larger, thicker wipe [with embossed design] (<i>may be used for 6 months on marketed label</i>)
New thicker wipe with embossed design (<i>may be used for 6 months on marketed label</i>)	Non-scratching [wipe]
Nonwoven disposable cloth	Picks up [particles] (dust) [dirt] [hair] [crumbs]
Strong, durable low-lint wipe [designed for sensitive equipment surfaces]	Strong, durable embossed textured wipe deodorizes
[Strong,] wipe helps remove dirt and grime from surfaces	[Strong,] wipe helps remove [dried] blood [and] [bodily fluids] from surfaces
Tear at perforation	Textured embossed design [deodorizes hard, non-porous surfaces]
Test wipe on small inconspicuous area first	Tear resistant
Thick, textured wipe with embossed design	Thick[,] [absorbent][Extra [Large][or Small] wipe
Thick [strong] wipe [material]	Wet wipes
[Wiping] [soft] side for disinfecting	X% bigger [quilted] [wipes] [vs. X" x Y" wipes]
X# [pre-saturated] towelettes [X" x Y"]	X" x Y" [wipes]

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Other Product Related Claims	
After use, just toss wipe(s) away	A [Sani-Surface®] [Sani-Cloth®] Brand
Always ready to use	A nonwoven disposable cloth for use [in hospitals] [other critical care areas] [or insert area of use facility] where control between treated surfaces is required.
Brought to you by [the makers of] [product name] [Sani-Cloth®] [PDI] [Sani Professional] [products] [brand]	Can help reduce cross contamination on treated hard, nonporous surfaces
Compatible with a wide variety of surfaces	Convenient
Delivers [consistent][specific] [amount of solution] concentration every time[!]	[Designed] [for] [with] [the] Environmental Services [EVS][ES][Housekeeping][Services] Professional[s] [in] [mind][!]
[Designed] For daily use [or Use for daily] [or] [discharge] cleaning [in Healthcare facilities]	[Designed] For [isolation][or terminal] cleaning [in healthcare facilities]
Designed for healthcare	Does not require [the hassle of] dispensing systems
Do not use on natural marble, windows, unpainted wood, clear plastic, or colored grout.	Effective [every day] [multisurface] [all facilities] [cleaner][disinfectant]
[Excellent] [Broad] surface compatibility	Effective cleaning on dried blood
Eliminates daily mixing and measuring	[EVS][ES] [Environmental Services] [Housekeeping][Services] use
Environmental services use	Expiration date [or EXP] [insert date]
Exclusive to PDI, Inc.	For [hospital] [healthcare] use
For direct application	[For] nonfood contact surfaces [only]
[For] daily use	From the makers of Sani-Cloth® [Brand][products]
Hospital [or insert area of use facility from page 6 - 7] [disinfectant] [disinfection] [disinfectant-cleaner]	[Ideal] for use on high-touch, hard, nonporous surfaces
Ideal product form for use around patients and staff	© [insert year] [insert company name]
Just [pull] wipe and toss	Large[r] Surface[s]

Made [or manufactured] in [USA] [Of Domestic and [Foreign] [Imported] Materials] [Made in [insert country]]	Meets disinfection recommendations from OSHA Bloodborne Pathogen Standard [or AHE Practice Guidance for environmental cleaning] [CDC Guidelines for disinfection and sterilization in healthcare settings]
Not for sale in [insert name of state(s)]	No sponges, no rags, no buckets, no mess
Not available in private label	Not for sale [or use] after [insert date]
Reduce cross contamination on hard, nonporous surfaces	Use by [insert date]
Use on hard, nonporous surfaces only: [stainless steel] [Formica®] [glass] [glass tables] [glazed tile] [Test solution on a small inconspicuous area first.] [Formica® is a registered trademark of The Diller Corporation.]	Value
Versatile	Where control of cross contamination between treated surfaces is of prime importance
[Product name] is a germicidal wipe containing a Hydrogen peroxide based solution. Recommended for use in hospitals and other critical care areas where the control of the hazards of cross-contamination between treated surfaces is required. Use on hard, nonporous surfaces and equipment listed on this label made of stainless steel, plastic, Formica® and glass. [Formica® is a registered trademark of The Diller Corporation.]	

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New (may be used for 6 months on marketed label)

Note: The following claims can be used only for 6 months]

[Better] [New] [Improved] [Stronger] [Thicker] Wipe [!]

[Better] [new] [&] [improved] [dispensing] lid [closure] [cap] [package] [dispensing] [better] [than before]

[Cleans] [better than ever]

New and improved

[New] [Package] [packaging] uses [x%] less material (plastic) [then] [when compared to] [regular] containers [or canisters]

New thicker and larger embossed wipe cleans more surface area

New disinfectant with sporicidal activity ^[^]wipe [(^ [C. difficile] [or C. difficile] [or C. diff] [spores])]

New Hydrogen Peroxide [H₂O₂] Formulation

New Disinfectant With Sporicidal Activity ^[^] Hydrogen Peroxide [H₂O₂] Formulation [(^ [Clostridium difficile] [or C. difficile] [or C. diff] [spores])]

[Now] [Reinforced] [With] Quilted [strength]

Now with [%] more towel

Now with [#] more wipes

[Stronger] more durable [wipe]

Thick[er] [wipe] [with] cloth-like texture

X% [Bigger] [larger] [quilted] wipes

[X%] thicker wipes

[Graphics depicting use sites listed on this label can appear on product label and labeling.]

[The following graphics and statements are optional.

They may be placed anywhere on label/container.]

The following is optional and may appear as verbiage or as a graphic:

- H₂O₂ [Hydrogen Peroxide] formulation
- Effective against [C. difficile][C. diff][Clostridium difficile][spores]
- Effective against [Candida auris] [or C. auris] [in one [or 1 minute]
- H₂O₂ [Hydrogen Peroxide] formulation effective against [C. difficile][C. diff] [Clostridium difficile][spores]
- Disinfectant With Sporicidal Activity formulation effective against [C. difficile][C. diff] [Clostridium difficile][spores]
- Bactericidal formulation effective against [insert microorganism]
- Virucidal* formulation effective against [insert microorganism]
- Bactericidal, Virucidal*, Fungicidal, Tuberculocidal [1 minute or 60 seconds]
- Disinfectant with sporicidal^[^] activity formula
- Do not flush
- FOR USE ON HARD, NONPOROUS SURFACES ONLY
- Do not freeze
- Do not allow to freeze
- Not a Baby Wipe
- Not a Skin Wipe
- Not For Use On Skin

[(^ [Clostridium difficile] [or C. difficile] [spores])]

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This graphic shows use of the wipe dispenser



[The following are company logos for use on PDI product labels. The purpose of the logo is for easy recognition of PDI products in the marketplace.]



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